

# **CGMS<sup>®</sup> *iPro*<sup>™</sup> Continuous Glucose Recorder**

**User Guide**

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This product is covered by at least the following U.S. Patent Nos: 5,586,533; 5,954,643; 6,248,067; 6,368,141; 6,418,332; 6,809,653. U.S., International and/or foreign patents are pending.



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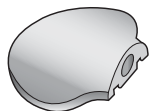
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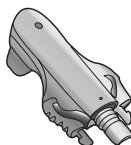
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The CGMS® iPro™ Continuous Glucose Recorder continuously collects and records patient glucose data. This data is then downloaded to the Solutions® Software for CGMS® iPro™ Continuous Glucose Recorder where it can be used to create clinical reports. Performance data for this device can be found in the Solutions Software user guide.



**Digital Recorder**



**Tester**



**Charger**



**CGMS iPro Wand**

### CGMS iPro Continuous Glucose Recorder components

A complete CGMS iPro Continuous Glucose Recorder kit includes:

- CGMS iPro Digital Recorder (MMT-7709)
- Sen-serter® device (MMT-7500) *(not shown)*
- Blue Tester (MMT-7706)
- AAA alkaline battery(ies), size E92, type LR03 *(not shown)*
- Charger (MMT-7705)
- CGMS iPro Magnetic Wand (MMT-7712)
- Occlusive dressing *(not shown)*

You will also need the following components:

- COMLINK™ CGMS iPro™ (MMT-7304NPRO/MMT-7304WPRO)

- Solutions® Software for CGMS® iPro™ Continuous Glucose Recorder (MMT-7319)

### Optional components

The following optional components allow you to connect up to four serial devices to your PC at once. For example, you can connect a meter and a COMLINK iPro to your PC at the same time.

- Manual serial data switch box (Part number: 1112058-003)
- Serial interface cable for the manual serial data switch box (MMT-7324)

### Indications for use

The CGMS iPro Digital Recorder is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose-monitoring devices. The information collected by the digital recorder may be downloaded and displayed on a computer and reviewed by healthcare professionals. This information may allow identification of patterns of glucose-level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions.

The CGMS iPro Digital Recorder:

- Is intended for prescription use only.
- Will not allow readings to be made available directly to patients in real time.
- Provides readings that will be available for review by physicians after the recording interval (72 hours).
- Is currently intended for occasional rather than everyday use.
- Is to be used only as a supplement to, and not a replacement for, standard invasive measurement.
- Is not intended to change patient management based on the numbers generated, but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take fingerstick glucose measurements to better manage the patient.

The glucose sensor, tester, charger, and CGMS iPro Wand are intended for use with the CGMS iPro Digital Recorder. The Sen-serter® device is indicated only for insertion of the Medtronic MiniMed glucose sensor.

## Contraindications

Do not use magnetic mattress pads while wearing the CGMS *iPro* Digital Recorder. The magnetic mattress pad will cause the digital recorder to frequently enter a transmission mode that will quickly drain the rechargeable battery and will temporarily disable data collection. Therefore, there will be sensor data gaps and the digital recorder is likely to not function for the entire 3-day duration. The magnetic mattress pad will not, however, affect the accuracy of the sensor readings that are collected, nor will it lead to any unsafe conditions.

Do not expose your digital recorder to MRI equipment or other devices that generate strong magnetic fields. If your digital recorder is inadvertently exposed to a strong magnetic field, discontinue use and contact your physician.

## Warnings

Product contains small parts and may pose a choking hazard for young children.

### Sensor

The glucose sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at the insertion site, or if you experience unexplained fever.

An optional occlusive dressing should be removed if irritation or reaction to the tape develops.

The glucose sensor may create special needs regarding your patients' medical conditions or medications. Healthcare professionals should discuss this with their patients before they use the glucose sensor.

Wait five minutes after glucose sensor insertion before setting up the CGMS *iPro* Digital Recorder with the Solutions CGMS *iPro*.

- Make sure that the site is not bleeding before connection. If any blood gets inside the digital recorder connector, the digital recorder must be discarded.
- If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, attach the digital recorder to the glucose sensor.
- If bleeding persists after three minutes, remove the glucose sensor and discard. Insert a new glucose sensor in a different location.

Contact your local country representative or the 24 Hour HelpLine (US) if you experience any adverse reactions associated with the digital recorder or glucose sensor.

### **CGMS *iPro* Magnetic Wand interference**

Do not store the CGMS *iPro* Magnetic Wand or any other magnet within 1.5 inches (3.8 cm) of the CGMS *iPro* Digital Recorder. Premature battery discharge may occur.

Do not place the CGMS *iPro* Magnetic Wand or any other magnet within 1.5 inches (3.8 cm) of the CGMS *iPro* Digital Recorder except while performing patient set-up and data download procedures. Premature battery discharge may occur.

### **CGMS *iPro* Magnetic Wand interference with insulin pumps**

Do not place the CGMS *iPro* Magnetic Wand directly on any insulin pump. Incorrect pump operation may occur.

Do not insert the glucose sensor with attached CGMS *iPro* Digital Recorder closer than two to three inches (5.08 - 7.62 cm) from the insulin pump. The use of the CGMS *iPro* Magnetic Wand may inadvertently cause incorrect operation of the pump.

### **CGMS *iPro* Magnetic Wand interference with PC hard drives**

Do not place the CGMS *iPro* Magnetic Wand on your PC or external hard drives, as the magnetic field may impact the integrity of the data files stored there.

### **Other electromagnetic interference**

The CGMS *iPro* Digital Recorder is designed to withstand common electromagnetic interference, including airport security systems.

## **Precautions**

If performing multiple CGMS *iPro* Digital Recorder studies on the same patient, establish a rotation schedule for choosing new glucose sensor sites. Avoid sites that are constrained by clothing, have scar tissue, or are subject to rigorous movement during exercise.

If any blood gets inside the digital recorder connector, the digital recorder must be discarded.

If you do not plan to use the digital recorder for at least 30 days, connect it to the charger for storage. The charger will not keep the digital recorder charged, but it will slow the digital recorder's battery discharge. Remove the digital recorder from the charger at least once every 60 days, wait at least one minute, then reconnect the digital recorder to the charger. To use the digital recorder after it has been stored, disconnect it from the charger, wait at least one minute, then reconnect it again to start the charging process. It may take up to eight hours to fully charge a digital recorder that has been stored for more than 30 days.



## FCC notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility.

This device complies with Part 15 Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

The CGMS *iPro* Digital Recorder does not interfere with any radio frequency signals transmitted from outside sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

**Important: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.**

## RF interference from other wireless devices

Common consumer wireless devices that transmit in the same 916.5MHz/868.35MHz frequency band used by the MMT-7709 CGMS *iPro* Digital Recorder (DR) transmitter may prevent the DR transmitter from downloading appropriately to Solutions CGMS *iPro* through the MMT-7304NPRO/MMT-7304WPRO COMLINK *iPro* receiver. Most cellular (mobile) phones and 900 MHz cordless phones, when transmitting or receiving, may cause significant disruption to communication between the DR transmitter and the COMLINK *iPro* receiver. It is likely that other wireless devices co-existing in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to your digital recorder.

Communication problems between the *iPro* DR transmitter and COMLINK *iPro* receiver can usually be resolved or corrected by:

- making sure that the transmitter and receiver are as close to each other as possible, and no further apart than six feet (1.8 meters),
- turning off, or moving away from, other RF wireless transmitting devices,
- reorienting or relocating the DR transmitter and/or COMLINK *iPro* receiver.

Testing conducted with several different cellular phones suggests that interference will not be a problem if the phone is at least 12 inches (31 cm) from the DR transmitter or

COMLINK *iPro* receiver when used (greater separation distance may be required for certain devices).

## Assistance

### United States

Medtronic provides a 24 Hour HelpLine for product assistance for U.S. users. The 24 Hour HelpLine is staffed with technicians who are trained in the setup and use of the CGMS *iPro* Continuous Glucose Recorder and are able to answer your questions.

Department	Telephone number
24 Hour HelpLine, if calling from within the United States	(800) 646-4633
24 Hour HelpLine if calling from outside the United States	818-576-5555
MiniMed Web site	<a href="http://www.medtronicdiabetes.com">www.medtronicdiabetes.com</a>

### Other countries

For product assistance outside the U.S., please contact your local country representative. Refer to the enclosed Medtronic Diabetes International Contact Card for the Help Line in your area.

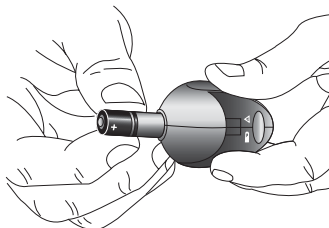
## Charger

**WARNING:** Always clean the digital recorder after removing it from the patient and before attaching it to the charger. See the cleaning instructions on page 20.

The digital recorder contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that indicates any problems during charging. If you see a red light, see the Troubleshooting section on page 18. The charger needs one AAA battery, size E92, type LR03, to operate. A new AAA battery contains enough power to recharge the digital recorder more than 40 times.

### Installing a new charger battery

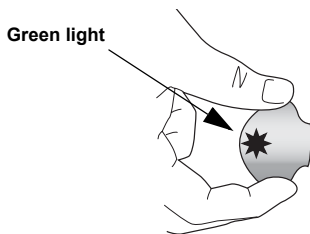
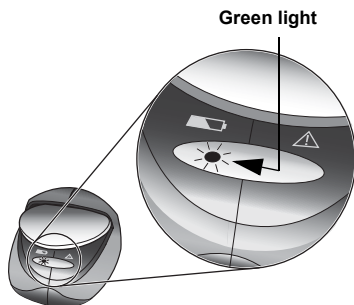
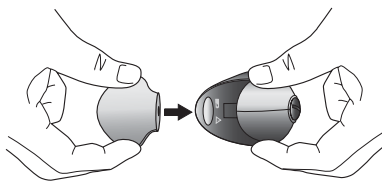
1. Remove the charger battery cap by turning it counter-clockwise 1/4 turn using a coin in the groove of the cap.
2. Insert a new AAA battery with the flat (-) end first. Make sure that you align the small bumps on the battery cap with the small notches in the charger's battery opening. Push in the cap all the way using a coin. Turn the cap clockwise 1/4 turn to close.
3. If the battery is installed incorrectly or is low, the charger will not work. Repeat the steps above using a new battery.



### Charging the digital recorder

Before using the digital recorder for the first time, you must fully charge the digital recorder battery which may take up to eight hours. It is recommended to recharge the digital recorder after each glucose sensor use. If you choose to recharge the digital recorder after a 3-day glucose sensor use, the charging time will be less than 20 minutes.

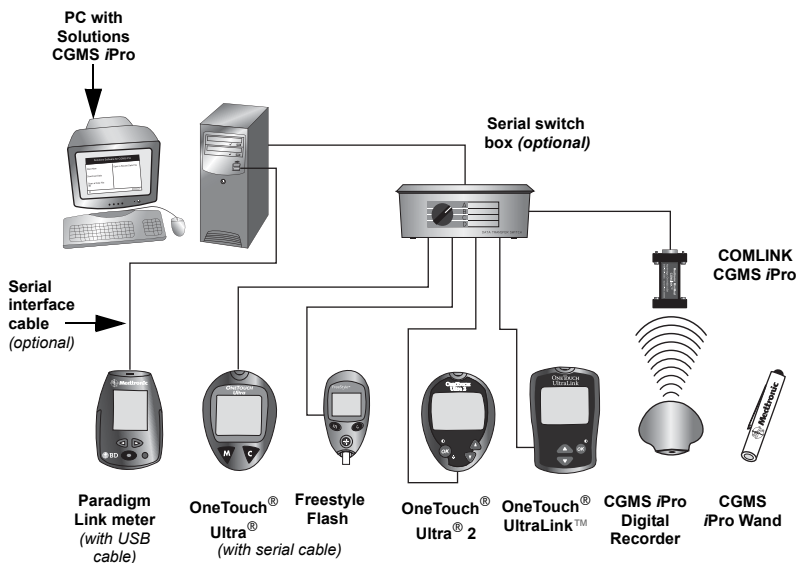
1. If a green light on the digital recorder is lit or flashing, do not connect it to the charger. The digital recorder will not charge with its green light on. Wait for the green light to turn off (approximately 30 seconds), then connect the digital recorder to the charger.
2. Connect the digital recorder to the charger by lining it up, flat side down, with the charger. Push the two components together fully. Always allow at least one minute before disconnecting the digital recorder from the charger or the digital recorder may not work properly. If you disconnect the digital recorder before one minute, reconnect it to the charger for at least one minute.
3. Within 10 seconds after the digital recorder is connected, a green light on the charger will flash for 1-2 seconds as the charger powers on. For the rest of the charging time, the charger's green light will flash in a continuing pattern of four flashes, pause, four flashes, pause.
4. When charging is complete, the green light on the charger will stay on, without flashing, for 15-20 seconds and then turn off.
5. After the green charger light turns off, disconnect the digital recorder from the charger. The green light on the digital recorder will flash for about five seconds, then turn off.
6. If the green light on the digital recorder does not flash, reconnect it to the charger for at least one minute.
7. After removing the digital recorder from the charger, wait at least one minute before connecting it to a sensor or tester.



## Hardware setup

The following diagram provides an example of how you will connect the components used with the CGMS iPro Digital Recorder. For information on setting up Solutions CGMS iPro, see the *Solutions Software for CGMS iPro Continuous Glucose Recorder User Guide*.

Make sure that your ComLink label says COMLINK CGMS iPro. A standard COMLINK will not work with the digital recorder.



The example above shows the Paradigm Link® meter connecting to the PC with a USB cable. This meter can also be connected with a serial cable.

## Supported meters

The following meters are supported:

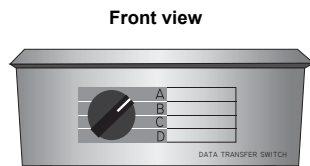
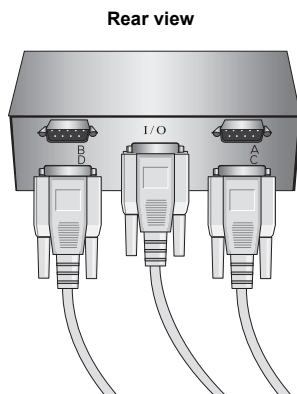
- Medtronic Paradigm Link
- Abbott Freestyle Flash®
- LifeScan OneTouch® Ultra®
- LifeScan OneTouch® UltraLink™
- LifeScan OneTouch® Ultra® 2

You can use a USB cable with the Paradigm Link meter only. You *must* use a serial cable to connect all other meters (even if the meter comes with an optional USB cable).

## Serial switch box

The optional four-port serial switch box allows you to connect up to four serial devices to your PC.

- Connect the device's serial cable to the A, B, C or D port on the back of the serial switch box. The example shows two device serial cables connected.
- Connect one end of the serial switch box cable to the I/O port (in the center). Connect the other end to the serial port on your PC.



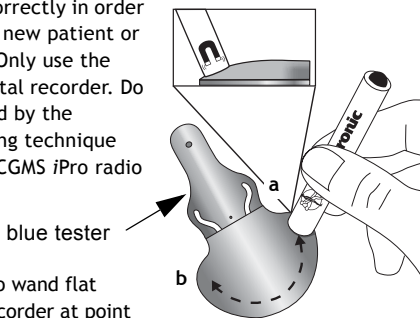
- To communicate with the PC, turn the switch box dial to the letter for the serial port (A, B, C or D) you want to use. For example, if a meter is connected to serial Port A and the COMLINK iPro to Port D, you can switch between A and D accordingly.

## Using the CGMS iPro digital recorder and CGMS iPro Wand

The CGMS iPro Digital Recorder contains a built-in two-way wireless radio that communicates with the COMLINK iPro during patient setup and data download. The radio operates as both a receiver and a transmitter.

The radio receiver is turned on by the iPro Wand that comes with your digital recorder. The silver end of the iPro Wand is a powerful magnet so it is important to keep it away from computers, credit cards, insulin pumps, glucose monitors and all other electronic media that can be affected by magnetic fields.

It is also important to use the iPro Wand correctly in order to turn on the digital recorder to set up a new patient or download data from the digital recorder. Only use the supplied CGMS iPro Wand to swipe the digital recorder. Do not use any other magnet. When prompted by the Solutions software, follow the wand swiping technique described below to properly activate the CGMS iPro radio receiver:



1. Place the silver, magnetic tip of the iPro wand flat against the surface of the iPro digital recorder at point (a) or point (b). You may swipe in either direction.
2. Move the wand slowly along the edge of the digital recorder from point to point. Take at least five seconds to complete the swiping process. You may swipe more than once, and change direction while swiping.
3. Always refer to the *Solutions Software for CGMS iPro Continuous Glucose Recorder User Guide* for complete instructions.

## Communicating with Solutions CGMS iPro

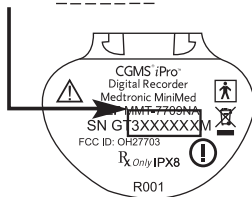
You use Solutions CGMS iPro to set up a new patient and to download data from the digital recorder. You should always refer the *Solutions Software for CGMS iPro Continuous Glucose Recorder User Guide* for complete instructions. The digital recorder and Solutions CGMS iPro must communicate during initialization and data transfer. This section provides an overview of how the components are used for each process.

**CAUTION:** This procedure describes how to connect the glucose sensor to the digital recorder. It is very important that you follow the sequence provided by Solutions CGMS iPro when setting up the device. *Solutions CGMS iPro* will indicate when to connect the devices. See your *Solutions Software for CGMS iPro Continuous Glucose Recorder User Guide* for more details.

### Setting up the digital recorder

1. Enter the digital recorder serial number into the *Solutions* software. The serial number is on the flat side of the digital recorder, as shown on the right. Enter only the seven numbers, not the letters, when setting up a new patient.

SN GT3XXXXXXM



### Connecting the glucose sensor

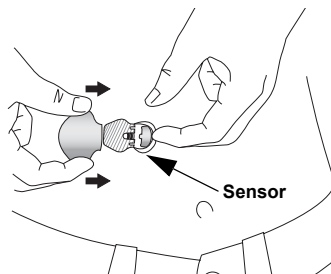
**CAUTION:** Do not connect the digital recorder to the glucose sensor until you are prompted to do so by Solutions CGMS iPro.

1. It is recommended that the digital recorder be fully charged before connecting it to the glucose sensor. If it is not fully charged, it may not flash when connected to the sensor and may not operate the sensor for the entire three days.
2. First insert the glucose sensor (follow the instructions provided with the glucose sensor). Check for bleeding. Make sure that bleeding has stopped (see Warnings on page 5 for details). **Do not connect the digital recorder at this time.**
3. The glucose sensor must be inserted in the patient's body for at least five minutes before connecting the digital recorder.
4. When prompted by the Solutions software, connect the digital recorder to a glucose sensor already inserted into the body. The digital recorder will not work if connected to a dry sensor (not inserted).



5. When connecting the digital recorder to the glucose sensor, touch the inserted glucose sensor at the back of the assembly to prevent movement.

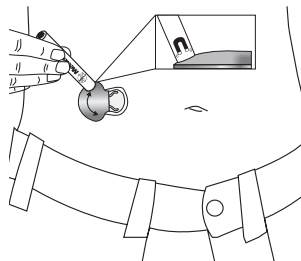
6. Hold the digital recorder as shown. Line up the two notches on both sides with the flexible side arms of the glucose sensor. The digital recorder flat side with the label should face the skin.



7. Slide the digital recorder onto the glucose sensor. Push it in firmly until the flexible side arms of the glucose sensor snap into the notches on both sides of the digital recorder. In the next 20 seconds the digital recorder will flash green for about 10 seconds. This indicates that the digital recorder is properly connected to a sensor and that it has enough battery power to work for at least three days.

8. If the digital recorder light does not flash, disconnect it from the glucose sensor. Wait for at least one minute and then reconnect. If the digital recorder light still does not flash, charge the digital recorder.

9. After the digital recorder light flashes green, you will be prompted by Solutions iPro to swipe the wand across the digital recorder. Please refer to Using the CGMS iPro Recorder and iPro Wand, on page 13, for correct swiping technique.



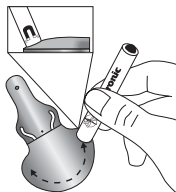
10. Solutions CGMS iPro will tell you if you have successfully started communication or if you need to repeat the start process.

11. After the digital recorder is successfully initialized by Solutions CGMS iPro, the Solutions software will prompt you to apply the recommended occlusive dressing over the digital recorder and the glucose sensor.

## Downloading data from the digital recorder

Follow the Solutions software instructions to download the patient's data from the digital recorder.

1. Setup the COMLINK iPro. Make sure that the COMLINK iPro is connected to your PC or the optional serial switch box.
2. If you are using the serial switch box, make sure that you select the communications port that corresponds to the COMLINK iPro. If the digital recorder has been disconnected from the sensor, then connect it to the blue tester. Whichever way you choose to download, make sure that the digital recorder is as close as possible to the COMLINK iPro to ensure a good RF connection. Click NEXT to continue.
3. When the software prompts you, swipe the digital recorder with the iPro Wand to start communication and begin the download.
4. After a successful data download, clean and dry the digital recorder, remove the tester, and connect the digital recorder to the charger.



## Calibrating Solutions CGMS iPro

The *Solutions* software must be calibrated with fingerstick measurements to maximize sensor reading accuracy. The *Solutions* software requires at least four fingerstick measurements per 24-hour period for each of the three-day study interval (a minimum total of 12 fingerstick measurements).

Be sure patients know to take fingerstick glucose measurements when their blood glucose is stable - such as before meals and at bedtime, and to avoid times such as right after eating, exercising or insulin delivery.

The *Solutions* software only accepts BG meter values between 2.2-22 mmol/L (40 and 400 mg/dL).

If patients use one of the *Solutions*-compatible BG meters listed in this user guide, the BG measurements will automatically download from the meter into the *Solutions* software during the download process.

Patients who use a non-compatible BG meter must log each BG meter value in the BG Meter and/or in their Patient Log sheet as soon as they take a reading. This allows the

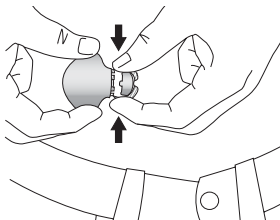
data to be manually entered into the *Solutions* software when the patient goes back to the doctor's office at the end of the three-day study.

### Bathing and swimming

After the digital recorder and the glucose sensor are connected, they form a water-tight seal to a depth of eight feet (2.4 meters) for up to 30 minutes. You can shower, bathe or swim without removing them. However, an occlusive dressing is recommended in order to reduce the risk of the sensor being pulled from the body.

### Disconnecting from the glucose sensor

1. Hold the digital recorder as shown, and pinch the flexible side arms of the glucose sensor between your thumb and forefinger.
2. Gently pull the digital recorder away from the glucose sensor assembly.

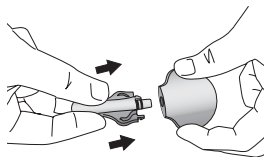


### Tester

The blue tester is used to test the digital recorder to make sure it is working. It is also used in place of an inserted sensor when the digital recorder is communicating with Solutions CGMS iPro (primarily during the data download process).

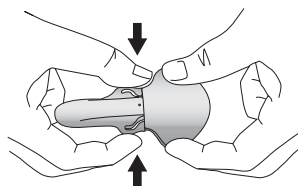
### Connecting the tester

1. Make sure the tester is clean before you use it.
2. Hold the digital recorder and the tester as shown. Line up the flat side of the tester with the flat side of the digital recorder.
3. Push the tester into the digital recorder. The flexible side arms of the tester should click into the notches on both sides of the digital recorder.
4. Within 20 seconds the green light on the digital recorder will flash for about 10 seconds when properly connected.
5. Check that the digital recorder is communicating with Solutions CGMS iPro. See your *Solutions Software for CGMS iPro Continuous Glucose Recorder User Guide* for more details.



## Disconnecting the tester

1. Hold the digital recorder body as shown and pinch the side arms of the tester.
2. With the tester arms pinched, gently pull the digital recorder away from the tester.
3. To save the digital recorder's battery life, disconnect the tester when you are finished communicating with Solutions CGMS *iPro*.



## Troubleshooting

**Question:** Why did the flashing green charger light turn off and a longer flashing red charger light turn on during charging?

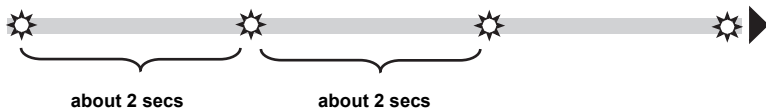
### Digital recorder low battery



**Answer:** The digital recorder battery is very low. Leave the digital recorder on the charger for eight hours to completely recharge. If the red light is still flashing after eight hours, call the 24 Hour Helpline or your local representative. It may be time to replace your digital recorder.

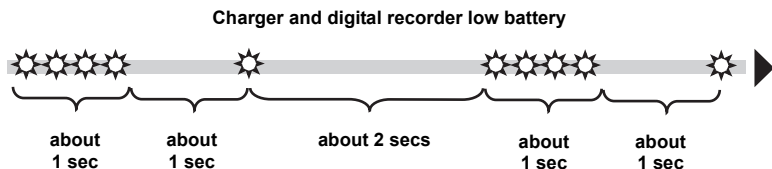
**Question:** Why do I see slow flashing red lights on the charger?

### Charger low battery



**Answer:** Your charger battery is low. Make sure the digital recorder is not connected to the charger and replace the charger battery with a new AAA battery.

**Question:** Why do I see a mix of quick and long flashing red lights on the charger?



**Answer:** Your charger *and* digital recorder batteries are very low. Replace the charger's AAA battery. If you now get the pattern for very low digital recorder battery, leave the digital recorder on the charger for eight hours to recharge. If the red light is still flashing after eight hours, call the 24 Hour HelpLine or your local representative. It may be time to replace your digital recorder.

**Question:** I had my digital recorder on the charger for a day. Will this damage my digital recorder?

**Answer:** It will not damage the digital recorder. You cannot overcharge it.

**Question:** What should I do if the digital recorder green light did not flash after removing it from the charger?

**Answer:** Reconnect the digital recorder to the charger for at least **one minute**. Remove it and watch the digital recorder green light flash and then turn off.

**Question:** What should I do if the digital recorder green light does not flash when connected to the glucose sensor?

**Answer:** Is the glucose sensor inserted in the body? If so, has it been inserted for at least five minutes?

- If it is **not inserted**, the digital recorder will not flash green or record glucose data.
- If it **has been inserted for less than five minutes**, the digital recorder may not flash green or record glucose data. In this case, you need to disconnect the digital recorder from the glucose sensor. Wait five minutes and then reconnect. If the green light still does not flash, charge the digital recorder.
- If it **has been inserted for more than five minutes**, you need to disconnect the digital recorder from the glucose sensor. Wait for at least one minute and then reconnect. If the green light still does not flash, charge the digital recorder.

**Question:** Why didn't I see the digital recorder green light flash after connecting it to the blue tester?

**Answer:** Check the connection. If you still do not see a green light flash, fully recharge the digital recorder battery. Test the digital recorder with the tester, as described on page 17 (make sure the tester is clean before using). If you still do not see a green light flash, clean the tester connector. If you still do not see a green light flash, call the 24 Hour Helpline or your local representative. It may be time to replace your digital recorder.

## **Cleaning the CGMS *iPro* Digital Recorder**

The CGMS *iPro* Digital Recorder is intended for multiple patient use. Follow this procedure to clean the digital recorder after each patient use.

### **CAUTIONS:**

- The charger and the tester are NOT watertight. Do NOT immerse in water.
  - Do NOT discard the digital recorder in a medical waste container or otherwise subject it to incineration. The digital recorder contains a battery which may explode upon incineration.
1. Attach the tester to the digital recorder to make sure that NEITHER water NOR disinfectant NOR alcohol gets inside the digital recorder's connector.
  2. Dampen a clean cloth with a mild liquid soap solution. Wipe the outside of the digital recorder.
  3. Rinse the digital recorder under warm tap water but do NOT get water inside the connector. If you get water inside the connector, shake the water out and allow it to air dry.
  4. Apply three to four drops of a quaternary ammonium compound disinfectant (for example, Cavicide®) on a clean, dry cloth and wipe the digital recorder.
  5. Hold the digital recorder and rinse with 70% isopropyl alcohol.
  6. If there is adhesive residue on the digital recorder, you can remove it with Detachol® adhesive remover between each patient use.
  7. Disconnect the tester from the digital recorder.
  8. Place the digital recorder on a clean, dry, non-shedding cloth and air dry.

9. After it is completely dry, connect it to a charger and place it in a sealed bag labeled with the cleaning date (see label example to the right).

**CAUTION:** If there is any blood inside the connector, the digital recorder must be discarded. Dispose of the digital recorder according to the local regulations for battery disposal (non-incineration).

#### Cleaning label

Device:  
Date:  
Method of decontamination:  
Wash:  
Disinfectant:

### Storage

If you do not plan to use the digital recorder for at least 30 days, connect it to the charger for storage. The charger will not keep the digital recorder charged, but it will slow the digital recorder's battery discharge. Remove the digital recorder from the charger at least once every 60 days, wait at least one minute, then reconnect the digital recorder to the charger. To use the digital recorder after it has been stored, disconnect it from the charger, wait at least one minute, then reconnect it again to start the charging process. It may take up to eight hours to fully charge a digital recorder that has been stored for more than 30 days.

## Guidance and manufacturer's declaration

### Guidance and Manufacturers Declaration - Electromagnetic Emissions

The CGMS iPro Digital Recorder (MMT-7709) is intended for use in the electromagnetic environment specified below. The customer or the user of the CGMS iPro Digital Recorder should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The CGMS iPro Digital Recorder uses RF energy only for system communication functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class Bv	The CGMS iPro Digital Recorder is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	
		<b>NOTE:</b> The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since the CGMS iPro Digital Recorder is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.



## Guidance and Manufacturers Declaration - Electromagnetic Immunity


The CGMS iPro Digital Recorder (MMT-7709) is intended for use in the electromagnetic environment specified below. The customer or the user of the CGMS iPro Digital Recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact  ±8 kV air	Not applicable  ±30 kV air (<5% relative humidity)	The CGMS iPro Digital Recorder should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines  ±1 kV for input/output lines	Not applicable  Not applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)  ±2 kV line(s) to earth	Not applicable  Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle  40% $U_T$ (60% dip in $U_T$ ) for 5 cycles  70% $U_T$ (30% dip in $U_T$ ) for 25 cycle  <5% $U_T$ (>95% dip in $U_T$ ) for 5 seconds	Not applicable  Not applicable  Not applicable  Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**NOTE:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

## Guidance and Manufacturers Declaration - Electromagnetic Immunity

The CGMS iPro Digital Recorder (MMT-7709) is intended for use in the electromagnetic environment specified below. The customer or user of the CGMS iPro Digital Recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the CGMS iPro Digital Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = 1.2 \sqrt{P}$ 50 MHz to 80 MHz  $d = 2.3 \sqrt{P}$ 80 MHz to 6 GHz  Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 6GHz	3 V/m	

**NOTE:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CGMS iPro Digital Recorder is used exceeds the applicable RF compliance level above, the CGMS iPro Digital Recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CGMS iPro Digital Recorder.

## Recommended separation distances between portable and mobile RF communications equipment and the CGMS iPro Digital Recorder (MMT-7709)

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the CGMS iPro Digital Recorder. The CGMS iPro Digital Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or users of the CGMS iPro Digital Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CGMS iPro Digital Recorder as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 6GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.74
1	1.2	2.3
10	3.8	7.4
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $p$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Specifications

<b>Biocompatibility</b>	Digital Recorder: Complies with ISO 10993-1 for body contact
<b>Operating Conditions</b>	Digital Recorder Temperature: +32° to +122° F (0° to 50° C) Digital Recorder Relative Humidity: 10% to 95% with no condensation Charger Temperature: +50° to +104° F (10° to 40° C) Charger Relative Humidity: 30% to 75% with no condensation
<b>Storage Conditions</b>	Digital Recorder Temperature: -4° to +131° F (-20° to +55° C) Digital Recorder Relative Humidity: 10% to 100% with condensation Charger Temperature: +14° to +122° F (-10° to +50° C) Charger Relative Humidity: 10% to 95% with no condensation
<b>Battery Life</b>	Digital Recorder: 14 days of continuous glucose monitoring immediately following a full charge Charger: Completes 40 typical charging operations using a new AAA battery
<b>Digital Recorder Frequency</b>	MMT-7709NA - 916.5 MHz MMT-7709WW - 868.35MHz
<b>Digital Recorder Dimensions and Weight</b>	Width: 1.40 inches (3.56 centimeters) Length: 1.12 inches (2.84 centimeters) Height: 0.37 inches (0.94 centimeters) Weight: 0.2 ounces (5.67 grams)
<b>ComLink iPro Frequency</b>	MMT-7304NPRO - 916.5 MHz MMT-7304WPRO - 868.35 MHz

## Warranty, United States

Medtronic MiniMed warrants the Medtronic CGMS *iPro* Digital Recorder and charger to the purchaser of the product against defects in material and workmanship for a period of six months from the date of purchase.

During the warranty period, Medtronic MiniMed will repair or replace, at its discretion, any defective CGMS *iPro* Digital Recorder or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a CGMS *iPro* Digital Recorder or charger is repaired or replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic CGMS *iPro* Digital Recorder or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the CGMS *iPro* Digital Recorder or charger by the user, or third parties, after the date of sale;
- If service or repairs are performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in fluid, physical abuse (such as dropping); or
- If blood or water has entered the inside of the CGMS *iPro* Digital Recorder connector.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to glucose sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any defects in material or workmanship in the product. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, punitive or special damages of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded and specifically disclaimed, including, but not limited to, any warranty of merchantability or fitness for a particular purpose.

## Warranty, Other countries

Medtronic MiniMed warrants the Medtronic CGMS *iPro* Digital Recorder and charger to the purchaser of the product against defects in material and workmanship for a period of six months from the date of purchase.

During the warranty period, Medtronic MiniMed will repair or replace, at its discretion, any defective CGMS *iPro* Digital Recorder or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a CGMS *iPro* Digital Recorder or charger is repaired or replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic CGMS *iPro* Digital Recorder or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:









- If damage results from changes or modifications made to the CGMS *iPro* Digital Recorder or charger by the user, or third parties, after the date of sale;
- If service or repairs are performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in fluid, physical abuse (such as dropping); or
- If blood or water has entered the inside of the CGMS *iPro* Digital Recorder connector.




This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to glucose sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any defects in material or workmanship in the product. Any statutory rights granted to consumers under any applicable legislation are reserved. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, punitive or special damages of any nature or kind caused by or arising out of a defect in the product.

All other warranties, except any applicable mandatory statutory warranties, expressed or implied, are excluded and specifically disclaimed, including, but not limited to, any warranty of merchantability or fitness for a particular purpose.

## Icon table

Serial Number:	SN
Catalogue Number:	REF
One per container/package:	(1X)
Date of Manufacture:	
Manufacturer:	
Fragile Product:	
Attention: See Instructions for use:	
Temperature Range:	
Radio communication:	
Configuration:	CONF
Type BF Device (Protection from electrical shock):	
CGMS iPro Digital Recorder: Protected against the effects of continuous immersion in water (eight feet or 2.4 meters immersion for 30 minutes):	IPX8
Contains magnet:	
Signifies compliance with Industry Canada EMC and Radio communications requirements:	IC

CE mark by notified body as a medical device:	
CE mark as a radio transmitter under the R&TTE1999/5/EC/directives. Applies to 868.35 MHz (MMT-7709WW)	
Signifies compliance to Australian EMC and Radio communications requirements	



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